

Attachment D

JUN 18 2009

510(k) SUMMARY

FOR

DATASCOPE's 8Fr. 50cc IAB and ACCESSORIES

(Prepared in accordance with 21 CFR Part 807.92)

A. GENERAL INFORMATION

Submitter: Datascope Corp.
Address: 15 Law Drive
Fairfield, NJ 07004
Contact Person: Dolly Mistry
Global Regulatory Affairs Specialist
Phone: 973/244-6162
Fax: 973/244-6243
Date: May 15, 2009

B. DEVICE INFORMATION

Generic Name: Intra-Aortic Balloon Catheter (IAB)
Trade Name: Datascope's 8Fr. 50cc IAB and Accessories
Classification Name: Intra-Aortic Balloon Catheters (IABs) are classified
under 21CFR 870.3535

C. PREDICATE DEVICE INFORMATION

Datascope's 8Fr. 50cc IAB and Accessories are substantially equivalent to
the following marketed devices:

K041281 - Datascope's Linear 7.5Fr. IABs, S/E 6/7/04
K031569 - Datascope's CA40 8Fr. IABs, S/E 6/10/03
K013326 - Datascope's Fidelity 8Fr. IABs, S/E 11/02/01
K903930 - Datascope's Percor Stat DL 10.5Fr. 50cc IABs, S/E 3/17/97

D. DEVICE DESCRIPTION/INTENDED USE

Datascope's 8Fr. 50cc Intra-aortic Balloon Catheters and Accessories are used for intra-aortic balloon counterpulsation therapy in the aorta, whereby balloon inflation during diastole and deflation during systole increases blood supply to the heart muscle and decreases the work of the left ventricle. This is the **same intended use** as previously cleared for all other Datascope Intra-Aortic Balloon Catheters.

The intra-aortic balloon is placed in the descending aorta just below the subclavian artery and is intended to improve cardiovascular functioning during the following situations:

- Refractory unstable angina
- Impending infarction
- Acute MI
- Refractory ventricular failure
- Complications of acute MI (i.e. Acute MR or VSD, or papillary muscle rupture)
- Cardiogenic shock
- Support for diagnostic, percutaneous revascularization, and interventional procedures.
- Ischemia related intractable ventricular arrhythmias
- Septic shock
- Intraoperative pulsatile flow generation
- Weaning from bypass
- Cardiac support for non-cardiac surgery
- Prophylactic support in preparation for cardiac surgery
- Post surgical myocardial dysfunction/low cardiac output syndrome
- Myocardial contusion
- Mechanical bridge to other assist devices
- Cardiac support following correction of anatomical defects

E. TECHNOLOGICAL CHARACTERISTICS

Datascope's 8Fr. 50cc IABs and Accessories are substantially equivalent to the predicate devices with regard to intended use.

The modification to the Datascope's predicate 8Fr. IAB is dimensional only. The modified 8Fr. IAB membrane's volume will increase and the polyimide inner lumen dimension will decrease.

These modifications to the 8Fr. IABs and Accessories have been demonstrated not to affect safety or efficacy of the device.

F. NON-CLINICAL TESTS

The results of in-vitro tests conducted demonstrate that the functionality and performance characteristics of the device are comparable to the currently marketed devices.

G. CLINICAL TESTS

There has been no clinical evaluation of the new device in the U.S.

H. CONCLUSIONS

Based on the information presented in this 510(k) premarket notification, Datascope's 8Fr. 50cc IAB and Accessories are considered substantially equivalent to Datascope's currently marketed IABs and accessories.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUN 18 2009

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Datascope.Corp.
c/o Ms. Dolly Mistry
Global Regulatory Affairs
15 Law Drive
Fairfield, New Jersey 07004

Re: K091449

Trade/Device Name: Datascope Mega 50cc 8 Fr. Intra-Aortic Balloon (IAB) Catheter & Accessories

Regulation Number: 21 CFR 870.3535

Regulation Name: Intra-Aortic Balloon and Control System

Regulatory Class: Class III (three)

Product Code: DSP – system, balloon, intra-aortic and control

Dated: May 15, 2009

Received: May 18, 2009

Dear Ms. Mistry:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Page 2 - Ms. Dolly Mistry

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/cdrh/mdr/> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

Bram D. Zuckerman



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment B

Indications for Use Statement

510(k)

Number (If known)

K091449

Device Name

Datascope's 8Fr. 50cc Intra-Aortic Balloon Catheters and Accessories

Indications
for Use

Datascope's 8Fr. 50cc Intra-Aortic Balloon Catheters and Accessories
have the following indications for use:

- Refractory unstable angina
- Impending infarction
- Acute MI
- Refractory ventricular failure
- Complications of acute MI (i.e. Acute MR or VSD, or papillary muscle rupture)
- Cardiogenic shock
- Support for diagnostic, percutaneous revascularization, and interventional procedures.
- Ischemia related intractable ventricular arrhythmias
- Septic shock
- Intraoperative pulsatile flow generation
- Weaning from bypass
- Cardiac support for non-cardiac surgery
- Prophylactic support in preparation for cardiac surgery
- Post surgical myocardial dysfunction/low cardiac output syndrome
- Myocardial contusion
- Mechanical bridge to other assist devices
- Cardiac support following correction of anatomical defects

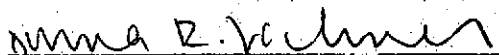
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Cardiovascular Devices

510(k) Number K091449